COMMONWEALTH OF VIRGINIA
Department of Health

ROBERT B. STROUBE, M.D., M.P.H.
STATE HEALTH COMMISSIONER (ACTING)

OFFICE OF ADJUDICATION

DOUGLAS R. HARRIS, J.D.

RECOMMENDATION TO THE STATE HEALTH COMMISSIONER
REGARDING CERTIFICATE OF PUBLIC NEED (COPN)
REQUEST NUMBER VA-6516
AUGUSTA HEALTH CARE, INC.
AUGUSTA COUNTY
INTRODUCTION OF RADIATION THERAPY SERVICES

A. FINDINGS OF FACT

1. On March 31, 2001, Augusta Health Care, Inc., a "501 (c)(3)" not-for-profit corporation with offices in Fishersville, applied for a certificate of public need (COPN), seeking authorization to introduce radiation therapy services at Augusta Medical Center (AMC) in Planning District (PD) 6, Health Planning Region (HPR) I.

2. Sections 32.1-102.1 and 32.1-102.3 of the Code of Virginia require that the "[i]ntroduction into an existing medical care facility of any new . . . radiation therapy . . . services must be approved by the State Health Commissioner through issuance of a COPN.

3. Augusta Health Care, Inc., owns AMC, a 255-bed general acute care, community hospital located approximately five miles northwest of the City of Waynesboro and approximately seven miles southeast of the City of Staunton.

4. AMC was formed in 1988 as a result of the merger of King's Daughters Hospital in Staunton and Waynesboro Community Hospital in Waynesboro. The primary service area of AMC includes

Augusta County and the cities of Staunton and Waynesboro, in PD 6. The hospital's secondary service area includes portions of Bath, Highland and Rockbridge counties, in PD 6, and the western portions of Nelson and Albemarle counties, in PD 10. According to the U.S. Census Bureau, population projections for the total service area total approximately 278,296 people in 2001 – an estimated 9.9 percent of whom are 65 years of age or older.

5. AMC is a member of Valiance Health, L.L.C., (Valiance), an alliance that also includes the University of Virginia Health System (UVa), Rockingham Memorial Hospital (RMH) and Stonewall Jackson Hospital (SJH). All four members are equal partners of Valiance. (Although a full partner in Valiance, Stonewall Jackson Hospital would not participate in this particular joint venture). Valiance has offices in Harrisonburg, also in PD 6. These hospitals' stated purpose for creating Valiance is to facilitate cooperative joint ventures beneficial to the partners and, derivatively, their patients.

6. AMC's inpatient services include medical-surgical services (for which 150 beds are dedicated), obstetrical services (16 beds dedicated), pediatrics services (8 beds), intensive care services (16 beds), psychiatric services (28 beds), rehabilitation services (8 beds) and skilled care services (29 beds). The hospital also provides an extensive complement of inpatient and outpatient services that consist of an emergency department, laboratory, respiratory and physical therapy, outpatient surgery, home health care, hospice, alcoholic treatment and detoxification, renal dialysis, outpatient medical rehabilitation, and diagnostic imaging (including ultrasound, computerized tomography, magnetic resonance imaging, radiology, mammography, and nuclear medicine).

7. AHC proposes to establish radiation therapy services on the campus of AMC. The proposed service would be housed in a new center devoted to the treatment of cancer to be built and connected to the front of the hospital. The cancer center would include space for AMC's existing medical oncology service and the proposed radiation therapy service. While AMC would continue to operate the oncology service, the radiation therapy service would be operated by Valiance.

8. The projected capital cost of this proposal is $6,564,402. Construction costs for the project would be financed from the accumulated reserves of AMC. Valiance would fund the costs of equipment for the radiation therapy center through conventional loan financing at a projected long term interest rate of 6.5 percent.

9. As the following table shows, in 1999, AMC ranked seventh of the thirteen hospitals in HPR I for its contribution to charity care – expressed as a percentage of total gross patient revenues, and ranked fifth for its contribution – expressed as a total monetary figure. AMC provided $2,487,703 in charity care – equivalent to 1.6 percent of its gross patient revenues, placing it at the median percentage for HPR I hospitals.

Charity Care in Health Planning Region I, 1999

Facility	Gross Patient Revenue	Total Charity Care	Percentage of Gross Patient Revenue
University of Virginia Medical Center	$572,775,834	$59,630,774	10.4
Culpeper Regional Hospital	47,280,013	1,220,126	2.6
Fauquier Hospital	68,369,543	1,620,415	2.4
Stonewall Jackson Hospital	22,732,645	524,147	2.3
Mary Washington Hospital	251,429,118	5,213,967	2.1
Warren Memorial Hospital	26,223,877	480,562	1.8
Augusta Medical Center	***155,540,490***	***2,487,703***	***1.6***
Winchester Medical Center	271,478,164	3,052,166	1.1
Rockingham Memorial Hospital	157,657,581	1,733,535	1.1
Bath County Community Hospital	5,177,252	45,272	0.9
Martha Jefferson Hospital	116,418,606	965,942	0.8
Shenandoah Memorial Hospital	31,911,242	239,491	0.8
Page Memorial Hospital	20,713,627	150,040	0.7
		HPR I Median	**1.6**

10. By letter dated September 18, 2001, the Virginia Department of Health, Division of Certificate of Public Need (DCOPN) notified AHC that DCOPN recommends conditional approval of the application to introduce radiation therapy services in PD 6.

11. By letter dated September 21, 2001, the director of the Virginia Department of Health, Center for Quality Health Care Services and Consumer Protection (within which DCOPN exists organizationally) notified AHC that the Department had determined a need for an informal fact-finding conference (IFFC) to discuss the proposed project. Specifically, this letter raised two general concerns in relation to the project: (i) Whether, in light of an underutilized radiation therapy service in Charlottesville, public need for the project exists; and (ii) Whether the cost of the project is excessive.

12. An IFFC was convened on October 30, 2001, in Richmond pursuant to Sections 9-6.14:11 and 32.1-201.6 of the Virginia Code to discuss this application. Augusta Health Care was represented by counsel at this IFFC.

B. DISCUSSION OF THE APPLICATIONS IN RELATION TO THE LAW

Virginia Code Section 32.1-102.3 B requires that, in determining whether a public need for a proposed project has been demonstrated, the State Health Commissioner shall review an application for a certificate of public need in relation to the twenty considerations enumerated in that section. The following is a discussion of the applications in relation to these considerations.

1. The recommendation and the reasons therefor of the appropriate regional health planning agency.

The Board of NWVHSA unanimously recommends approval of the proposed project, conditioned on "radiation therapy services equivalent to at least 1.8 percent of gross patient revenues for those services . . . [being] provided on a charity care basis." The NWVHSA recommends approval, under this condition, because:

(i) The project is consistent with all applicable State Medical Facilities plan standards "except one that is outdated;"

(ii) The proposed service would be "very beneficial to local residents;" and

(iii) The improvement in access the project would afford "is of paramount importance."

2. The relationship of the project to the applicable health plans of the regional health planning agency, the Virginia Health Planning Board and the Board of Health.

The applicable health plan is the portion of the State Medical Facilities Plan (SMFP) found in Part II of Chapter 340 of the Virginia Administrative Code (VAC, 12 VAC 5-340-10 *et seq*). (Text appearing under this consideration in italics has been selected from the SMFP and precedes discussion of the proposed project in relation to the selected text.)

12 VAC 5-340-20. Acceptability; consumer participation. Providers of radiation therapy services should provide a program of patient and family education regarding the nature of the patient's cancer and the available methods of diagnosis and treatment, and the medical, clinical, technical, psycho-social, financial, and nutritional aspects of the patient's condition and the family's role in caring for the patient.

Both UVa and RMH, AMC's Valiance partner-hospitals in this project, have been providing radiation therapy services for more than a decade. These hospitals have developed effective patient and family education programs that would provide insight and be available to AMC in developing a patient and family education program, complete with a library and Internet computer acess relating to the proposed project.

AMC represents that nurses and personnel with specific training and expertise in cancer care would provide services in staffing the project. Social services, nutritional counseling, psycho-social support and financial counseling also would be available to patients and their families and caregivers. AMC's oncology program already facilitates a cancer support group and this support group concept will be extended to radiation therapy patients and their families.

12 VAC 5-340-30. Accessibility; time; financial considerations. A. 1. Radiation therapy services should be available within the institution on a regularly scheduled basis, for a minimum of 40 hours a week.

AMC represents that radiation therapy services would be available at least 40 hours a week, and the program's hours of operation would be "scheduled for the benefit of patients."

2. Convenient hours of operation should be provided for the benefit of outpatients (early morning hours, lunch hours, evening hours, weekends).

AMC represents that it would ensure that patients can be treated in early morning and lunch time slots, and evening and weekend hours when necessary.

B. Radiation therapy services should be available within one hour normal driving time, under normal conditions, for 95 percent of the population.

AMC's primary service area is Augusta County and the cities of Waynesboro and Staunton. The hospital's secondary service area includes portions of Bath, Highland and Rockbridge counties, in PD 6, and the western portions of Nelson and Albemarle counties, in PD 10. The area, which AMC contends covers over 2,500 square miles, is traversed by Interstate highways 81 and 64. Interstate 81 is a major and heavily-used thoroughfare for the commercial transport by tractor-trailor of goods along the eastern seaboard, often making its use by occupants of passenger vehicles less than pleasant and, at times, stressful, marked by unpredictable delay and dangerous.

The inadequacy of Interstate 81 to meet current demand safely and effectively is demonstrated by the recent preparation of a preliminary six-year plan by the Virginia Department of Transportation. This plan involves numerous projects to widen and improve sections of Interstate 81, most of which are comprised of four lanes, in order to address the chronically high volume of commercial and passenger vehicle traffic it bears. Interstate 64 crosses through a pass over Afton Mountain between Waynesboro and Staunton. Traveling via Interstate 64 through this pass involves negotiating a gradient exceeding five degrees for several miles in both an easterly and a westerly direction and is often complicated by dense fog and severe winter weather conditions, only partially assuaged by a special roadway lighting system.

AMC is the only hospital located in Augusta County, which, in terms of land area, is the second largest county in Virginia, covering over 900 square miles of rural and mountainous terrain. AMC is also the nearest hospital to a large portion of geographically-dispersed residents in Bath, Highland, Rockbridge, Nelson, and Albemarle counties.

While a considerable portion of this area appears geographically proximate to AMC, travel times from points such as Buffalo Gap, Millboro Springs and Augusta Springs to AMC frequently exceed more than an hour. Travel by road in these areas involve negotiating the prevailing mountainous terrain over secondary state roads, some of which are paved with loose gravel. These physical barriers impede travel under the best conditions and are made more challenging by poor and inclement weather.

Testimony received at the IFFC, over a dozen letters from citizens and local leaders, and over two dozen statements volunteered by area residents and directed to the State Health Commissioner via email all attest to these difficulties and a certain cultural aversion to highway travel that may contribute to patients' deciding to forego prescribed treatment located at distant sites. Most of the email statements relate personal experience or a family member's experience with the challenges of traveling from home to receive radiation therapy treatments, consisting of daily treatments for several weeks, at UVa and RMH.

Delegate R. Steven Landes, representing the Twenty-fifth District in the Virginia House of Delegates and serving on the House Health, Welfare and Institutions Committee, appeared at the IFFC and shared his "complete and strong support" for the proposed project. In an accompanying letter, Delegate Landes eloquently spoke of the challenges residents of his district face when receiving radiation therapy services. "[T]hey must," he related,

> travel every day for six weeks to receive this life sustaining treatment. combined with that hardship, there is nausea, fatigue, breathing difficulties, time constraints as well a transportation burdens. Even with the best family support possible, these are insurmountable obstacles for some patients to endure. . . . Denial of this . . . [application would] seem not only unfair to our rural citizens but borders on discrimination to rural areas."

In a letter to the Commissioner dated September 28, 2001, Senator Emmett W. Hanger, Jr., representing the Twenty-fourth District in the Senate of Virginia, voiced his "unyielding support of AMC's plan. . . . AMC is able," he wrote

> to offer a continuum of cancer care for our citizens except for the ever-important radiation therapy. It is unfortunate that our citizens must trek over an hour each way to seek out this life-saving treatment. But what I find more disheartening, yet so preventable, is that many will forego radiation treatment altogether just so they do not have to put themselves and their caretakers through the rigors of making these trips everyday for six weeks. . . ."

In addition to enhancing access to radiation therapy services, the proposed project, as a venture of Valiance (which includes UVa and RMH), would enhance the provision of radiation therapy services in the extended area by allowing AMC, UVa and RMH to coordinate the provision of these services by providing them in the most accessible location for patients by directing them to the most conveniently accessible site under prevailing circumstances.

C. Radiation therapy services should be accessible to all patients in need of services without regard to their ability to pay or the payment source.

The applicant states that the proposed services will be available to all patients without regard to ability to pay. In 1999, AMC ranked seventh of the thirteen hospitals in HPR I for its contribution to charity care – expressed as a percentage of total gross patient revenues, and ranked fifth for its contribution to charity care – expressed as a total monetary figure. AMC provided $2,487,703 in charity care – equivalent to 1.6 percent of its gross patient revenues, placing it at the median percentage for HPR I hospitals.

D. Providers of radiation therapy services serving rural areas should facilitate the transport of patients residing in rural areas to needed radiation therapy services, directly or through coordinated efforts with other organizations. Preference will be given in the review of competing applications to applicants who can demonstrate a history of commitment to the development of transportation resources for rural populations.

AMC is one of the initial founders of and a major source of funding for the Coordinated Area Transportation System (CATS), a not-for-profit corporation that provides subsidized transportation for the residents of Augusta County and the cities of Staunton and Waynesboro. The applicant states that

AMC currently reimburses CATS $60,000 a year to provide transportation eight hours a day, five days a week for patients who do not have available means of transportation to the AMC.

In March 2000, AMC began operating an ambulance service that provides advanced life support and basic life support services. The ambulance service is available to all patients without regard to ability to pay. AMC also provides wheelchair van service and Medicaid taxi service.

12 VAC 5-340-40. Availability; need for new service; expanded; replacement of service. A. 1. No new radiation therapy service should be approved unless: (i) existing radiation therapy machines located in the health planning region in which the proposed new service is to be located were used for at least 320 cancer cases and at least 8,000 treatment visits for the relevant reporting period; and (ii) it can be reasonably projected that the new service will be used for 240 cancer patients and will perform at least 6,000 procedures by the third year without reducing the utilization of existing radiation therapy machines in the health planning region such that less than 8,000 procedures will be performed by any existing machine.

In 1999, four of the ten existing radiation therapy units in HPR I exceeded the 8,000-treatment visit standard included in the SMFP – last revised in 1993, and a total of six units provided in excess of 5,000 procedures annually, as shown in the following table. Overall, HPR I exhibited a utilization level in 1999 approaching 75 percent of this standard, averaging nearly 6,000 treatment visits per unit that year and an increase in utilization of nearly 20 percent from 1997 to 1999.

Utilization of Megavoltage Radiation Therapy Units in HPR I, 1997-1999

Facility	Number of Units	Total Number of Treatment Visits			Number of Treatment Visits per Unit		
		1997	1998	1999	1997	1998	1999
Rockingham Memorial	2	10,249	10,008	10,612	5,125	5,004	5,306
Winchester	2	10,654	14,263	17,195	5,327	7,132	8,598
Martha Jefferson	1	7,385	7,763	8,505	7,385	7,763	8,505
University of Virginia	4*	13,247	13,470	14,187	3,312	3,368	3,547
Mary Washington	1**	8,419	8,597	9,229	8,419	8,597	9,229
Total or Average	10	49,954	54,101	59,728	4,995	5,410	5,973

*Includes one older cobalt unit.

**Mary Washington Hospital received a COPN in April 2001 authorizing a second linear accelerator.

AMC points out that the methodology of treating cancer with radiation has changed since the capacity standard of the SMFP was drafted in the early 1990s and made effective in 1993, and that the provision is no longer adequate for gauging public need for radiation therapy services.

AMC contends that significant changes have occurred since 1993 in the types and numbers of cancers treated with radiation therapy and in the delivery of radiation therapy services. AMC observes that

> [r]adiation therapy has advanced significantly over the past decade, becoming . . . one of the most effective treatment options for a variety of types of cancer. It is the primary treatment for many kinds of cancer such

> as certain head and neck tumors, early stage Hodgkins disease and non-Hodgkin's lymphomas and certain cancers of the lung, breast, cervix, prostate, testes, bladder, thyroid and brain. In addition, radiation therapy is increasingly being prescribed for terminally ill patients in the form of palliative care.
>
> Other new radiation therapy applications combine radiation therapy with chemotherapy, and with surgery, which has also increased the use of radiation therapy. Another advance in radiation therapy treatment is hyperfractionated radiation, where the total dose of radiation is divided into smaller doses that are given more than once a day. This new advance has also increased the utilization of radiation therapy.
>
> One of the most important new techniques that is now considered state of the art radiation therapy treatment is Intensity Modulated Radiation Therapy, or IMRT. IMRT combines inverse treatment planning with optimization by computer and computer-controlled intensity modulation of the radiation beam during treatment to deliver 3D [three-dimensional] conformal radiation therapy. Although IMRT has significant benefit to patients in conserving normal tissue while providing more accurate targeting of the cancerous tissue, IMRT does substantially lengthen the treatment time or minutes per treatment by as much as two to three times greater than standard radiation therapy. When evaluating capacity per radiation therapy unit, these new technologies that extend the treatment time per patient need to be considered.

These advances in treatment indicate that substantial utilization of a radiation therapy machine can be achieved without necessarily approaching the utilization levels contemplated by this provision of the SMFP.

Based on an assumption that 50 percent of cancer cases are treatable with radiation therapy, AMC projects that the proposed service will treat 650 cases, which equates to an estimated 8,125 patient visits in the first year of operation, thereby indicating that the proposed project would exceed the projected utilization level suggested by the SMFP.

Notably, UVa and RMH stand to be affected most by approval of the proposed project, inasmuch as approval may decrease utilization of radiation therapy services at these facilities. Both facilities, however, are members of Valiance and clearly support the proposed project to establish radiation therapy services at AMC.

2. The number of megavoltage radiation therapy machines needed in a health planning region will be determined [using a need assessment methodology set forth in this provision].

This methodology considers several factors, including population, the prevailing cancer incident rate (provided by the Virginia Cancer Registry), and the assumption that 45 percent of new cancer cases are treatable with radiation therapy. The methodology is applied and summarized in

relation to the project proposed by AMC below, indicating an apparent surplus of 3.5 radiation therapy units in HPR I.

2004 Projected Need for Megavoltage Radiation Therapy Units in HPR I

Cancer Incidence Rate	Projected 2004 Population	Projected Radiation Therapy Cases	Radiation Therapy Units Needed	Existing Inventory of Radiation Therapy Units	**Surplus of Radiation Therapy Units**
0.00498	1,077,565	2,415	7.5	11*	**3.5**

*This figure does not include a specialized megavoltage device, a gamma knife, operated by UVa. The gamma knife is not a general-purpose radiation therapy machine, but is mainly dedicated to the treatment of certain brain tumors and circulatory malformations within the brain.

Notably, UVa is a regional cancer referral center as well as a National Cancer Institute Clinical Cancer Center and as such serves a much wider population than that indicated by the population base in HPR I. A portion of that facility's capacity, therefore, appears clearly unavailable to the population of AMC's service area.

A sizeable portion of both PDs 6 and 10 lies within AMC's service area. These planning districts exhibit an age-adjusted cancer incidence rate higher than HPR I overall, and Virginia as a whole, based on 1998 data. Within HPR I, the number of reported cancer cases in these two health districts had the highest percent increase in the age-adjusted incidence rate in the three year period ending in 1998.

Notably also, the Virginia Cancer Registry (VCR) cautions that its data, used to determine a cancer incident rate in the methodology summarized above, constitute a conservative account of cancer occurrence in Virginia because not all hospitals, outpatient facilities and private pathology laboratories report to VCR, a significant lag time in reporting and posting out-of-state cases can exist; and reporting artifacts due to reporting variability exist (*e.g.*, case ascertainment may be more complete in urban areas and for certain racial groups, cancer sites or diagnosis stages).

These conditions may impede an accurate assessment and reliable gauge of cancer occurrence in Virginia's population, and suggests that the number of cancer cases and the cancer incident rate in AMC's service area may be greater than the VCR data indicate.

Further, AMC notes, the actual utilization rate should be 50 to 60 percent, rather than 45, signifying a larger portion of new cancer cases treatable with radiation therapy. AMC also contends that the methodology for assessing need in the SMFP requires the use of the entire population of a health planning region, which, in this case, is spread across an area marked by "an artificial geographic boundary," and that the methodology fails to take account of the numerous changes in radiation therapy, some of which are discussed above, that have occurred since the methodology was devised in the early 1990s.

B. Notwithstanding the standards for approval of new radiation therapy services outlined above, consideration will be given to the approval of new radiation therapy services which will be located at a general hospital located 60 minutes or more driving time, under normal conditions, from any site at which radiation therapy services are available if it can be reasonably projected that the proposed new

services will perform at least 6,000 treatment procedures by the third year of operation, without reducing the utilization of existing machines located within 60 to 70 minutes driving time, under normal conditions, from the proposed new service location.

AMC in Fishersville is located within 30 miles or just over 35 minutes' driving time, under normal conditions, of both UVa in Charlottesville and RMH in Harrisonburg. The next nearest radiation therapy service is in Roanoke about 92 miles via Interstate 81 and over one and a half hours' driving time from Fishersville. Inclement weather and heavy highway traffic, however, may often increase these travel times considerably.

Despite a technical inability to comply with this provision, neither UVa nor RMH oppose the proposed project. In fact, both hospitals are partners in Valiance, which would operate the proposed radiation therapy service, and both hospitals support the approval of the proposed project as a beneficial means to provide needed services and better coordinate their provision.. The project promises a sizeable utilization and presents the availability of radiation therapy services to a predominantly rural and widely dispersed population impeded from gaining access to these services at existing facilities by geographic barriers that become magnified by the sensitive and weakened condition of radiation therapy patients and prevailing driving conditions.

AMC would provide the nearest radiation therapy service to a significant number of the residents of Bath, Highland, Rockbridge and Nelson counties. Much of the area covered by these counties is more than an hour's driving time from AMC and an even greater distance from UVa, in Charlottesville, and RMH, in Harrisonburg. The clear improvement in access that this proposal presents and its ability to provide these services in a facility located strategically to serve the intended area appears to outweigh the existence of potentially competing services at other facilities – none of which are opposing the proposed project.

In recommending approval of the project, the Board of the NWVHSA emphasized access concerns in recognizing the need for radiation therapy services at AMC. According to NWVHSA,

> [g]iven the expectations of most physicians and patients and the financial resources available to hospitals, marginal improvements in access and convenience are more highly valued than marginal improvements in the efficiency of medical care facilities use. [Further t]here is no strong reason . . . to believe that this project will have an impact on the facilities of RMH or UVa such that the financial feasibility or clinical effectiveness of those programs would be compromised.

12 VAC 5-340-50. Continuity; tumor registry; discharge and follow-up care. A. Facilities with radiation therapy services should participate in an accredited tumor registry.

The applicant states that AMC and its partner hospitals; UVa and RMH participate in the Virginia Tumor Registry (VTR), which is an accredited registry. In addition, AMC notes that the Commission on Cancer, American College of Surgeons accredits its existing oncology program.

1. All radiation therapy services should have written procedures and policies for discharge planning and follow-up care for the patient and family, which are part of the institution's overall discharge planning program.

The applicant states that as the proposed radiation therapy service will be operated by Valiance, of which UVa and RMH are partners, the discharge planning policies and procedures and follow-up care for the patient and family currently used by those hospitals' radiation therapy services will be adapted for use by the proposed AMC service. In addition, AMC already has a cancer program with policies and procedures for discharge planning and follow-up care.

2. All radiation therapy services should have established protocols for referring physicians to assure adequate post-operative diagnostic evaluation for radiation therapy patients.

To assure adequate post-operative diagnostic evaluation for patients availing themselves of the new service, the applicant proposes the use of the established protocols for referring physicians already in place at UVa and RMH.

12 VAC 5-340-60. Cost; cost comparability. The cost of radiation therapy services to be offered should be comparable to unit costs experienced by other similar radiation therapy services within the health planning region.

Four requests for COPNs authorizing the addition of radiation therapy services, including the present application from AMC, have been submitted for review in the past year; the other three have been approved. The table below shows a comparison of capital costs for these projects. The capital costs and charges associated with the AMC proposal are 40 percent higher than the median for the four projects, but includes costs for features and aspects of the project not necessarily included in the other three projects, along with a figure amounting to five percent of total costs that has been added to address construction and planning contingencies.

Projected Costs and Charges Regarding Recent Radiation Therapy Applications

Facility	Location	Projected Capital Costs	Projected Equipment Costs	Projected Charge per Treatment	
				First Year	Second Year
Shore Memorial Hospital	Nassawadox	$3,791,187	$2,000,000	$351	$362
Mary Washington Hospital*	Fredericksburg	301,814	270,261	492	483
Riverside Radiation Therapy Centers	Newport News	3,786,175	2,782,342	320	336
Augusta Medical Center	***Fishersville***	***6,564,402***	***3,764,402***	***585***	***585***
	Median	$3,788,681	$2,391,171	$336	$349

* Associated costs are low because the application proposed the re-commissioning of an existing linear accelerator and some remodeling and renovation of an existing vault.

AMC notes that it developed the cost and charge structure with the assistance of a national consultant with extensive experience in the development and operation of radiation therapy centers across the country. The proposed radiation therapy services would be established and constructed as

part of a larger project that includes expansion of AMC's medical oncology program. Placing the two projects in close proximity, AMC argues, creates

> significant savings in space that can be shared between the two programs. Shared administrative space, patient waiting, registration and library, billing, tumor registry, protocol office, staff lounge and conference space can be shared between the two programs and not duplicated. [Further,] AMC has an excellent track record of bringing facility projects in under budget, through tight management of the construction process.

More pointedly, AMC argues that the three applications, to which the AMC project has been compared, were "less detailed and, as such, are invalid barometers for gauging the reasonableness of AMC's equipment costs." In this respect, AMC appears to be asserting that various facets of the other projects may have been omitted from the applicants' proposals, in the belief that these facets were not reviewable under the COPN law, or that, without more complete elaboration, assurance that comparable levels of scope and detail have been used in devising the proposed projects is impossible.

Consistent with this general assertion, AMC observes in particular that the Mary Washington Hospital application is not comparable because it involves the recommissioning of an existing linear accelerator, and the attendant costs reflect the much smaller magnitude of such a project. Regarding the application submitted by Riverside Radiation Therapy Centers, AMC asserts that, for purposes of comparison, the linear accelerator AMC contemplates purchasing has a "distinct technological and capability difference [or advantage] in the range of photon and electron energy" over the accelerator proposed by Riverside. Further, AMC notes that, while its application includes $100,000 for calibration equipment and $50,000 for miscellaneous equipment, the Riverside application does not ascribe a cost addressing these needs.

AMC emphasizes that the equipment costs associated with its proposal are "the result of a deliberate, reasonable selection process undertaken by an equipment selection committee," comprised of physicians knowledgeable of medical physics and radiation oncology, which sought proposals from several equipment vendors in order to contain costs.

The total gross square footage of the AMC project is greater than the other three projects, reviewed in the last year and included in the table above, but comparable to a project completed at Greenville Hospital a few years ago. Half of the administrative space, to be shared with the existing medical oncology department at AMC, has been included in the proposed project costs. Total costs per square foot are reasonable and directly comparable to that of Shore Memorial Hospital's radiation therapy service, approved in October 2000.

In defending its proposal, AMC argues that the design of the proposed facility and its equipment selection "demonstrates meticulous planning to maximize efficiency," and that the "square footage [to be] developed was necessary and appropriate for the efficient and cost-effective operation of the radiation therapy unit." The Odell architectural firm, employed by AMC to design the proposed facility, has designed similar medical facilities across the country. Odell estimates that the proposed project will cost approximately $225 a square foot for the clinical portion of the radiation therapy facility, $135 a square foot for the administrative and other space shared with the oncology service and

$25 a square foot for the renovated portion of the shared space. AMC maintains that its project is "consistent with other projects of similar size and scope."

Analysis of AMC's proposed project appears to reveal that several prevailing conditions prevent a clear comparison of recent projects of similar size, scope, detail and capability difficult, and prohibit the devising of firm conclusions regarding the relative appropriateness and reasonableness of the various projects. While, ostensibly at least, the attendant costs of the proposed project appear high, they are not exorbitantly so, and may reflect a relatively greater level of sophistication of design and capability of equipment that could translate into more effective and conveniently-located service to the public. Regardless, the cost of the proposed project, as set forth in terms of cost per gross square foot, is reasonable.

12 VAC 5-340-70. Quality; staffing; financial considerations; patient care; support; care. A. 1. Radiation therapy services should have a medical director who is a licensed physician that is board certified in radiation oncology.

A medical director for the proposed radiation therapy service has not been appointed. The applicant represents, however, that a joint or rotating medical directorship will be established with one or both of the Valiance hospitals participating in the project. Both UVa and RMH already provide radiation therapy services under the direction of board certified medical directors. The applicant further submits that radiation oncologists from both UVa and RMH would provide services for the proposed facility. The proposed project presents the possibility to realize efficiencies in staffing, as medical and technical staff could be shifted among the three locations in response to need and volume.

2. The staffing pattern for radiation therapy services should include the following nonphysician personnel:

a. Dosimetrist(s);

The applicant represents that the proposed program will include a dosimetrist.

b. Radiation therapy technologists certified by the American Registry of Radiation Technologists;

The applicant states that radiation therapists certified by the American Registry of Radiation Technologists would staff the proposed service.

c. A radiation physicist, who is certified by the American Board of Radiology or its equivalent, or who holds an advanced degree in physics and has two to three years of full-time radiation therapy experience working under the direction of a certified radiation physicists; and

The applicant states that four radiation physicists from UVa would staff the proposed radiation therapy service. Three of these physicists are board-certified in radiological physics with 10 to 20 years' experience in the specialty. A fourth radiation physicist is a doctoral student specializing in medical physics.

d. A clinical registered nurse.

The proposed service would be staffed by the appropriate number of clinical registered nurses and other nursing related staff.

3. All radiation therapy services should have access to a medical social worker, psychologist, or psychiatrist to counsel those patients and families who need assistance with emotional and financial problems prior to and following radiation therapy services.

AMC states that the proposed radiation therapy service would include medical social workers, psychologists and psychiatrists to counsel patients and families.

B. 1. In addition to the radiation therapy machine, simulation equipment capable of precisely producing the geometric relations of the megavoltage equipment to be used for treatment of the patient should be available.

AMC represents that a computed tomography (CT) similator would be included for use by the radiation therapy center. The CT simulator includes a fully integrated software package that provides sophisticated three-dimensional (3D) CT simulation, and a 3D external beam radiation treatment planning system. By employing Intensity Modulated Radiation Therapy (IMRT), the proposed service would give patients the most precise radiotherapy possible, while sparing normal tissue. AMC intends the service to be equipped with the most advanced equipment currently available on the market.

2. Radiation therapy services should have access on-site to a computerized treatment planning system.

An on-site computerized treatment planning system would be included in the proposed project.

3. Radiation therapy services should have access to a custom block design and cutting system.

A custom block design and cutting system have been included in the proposed project.

C. 1. Facilities providing radiation therapy services should have diagnostic, laboratory, medical and surgical oncology services.

As a part of AMC –an existing community hospital, the proposed service would have direct access to pathology services. Medical and surgical oncology services, which are already provided at AMC, would be integrated into the proposed center. The applicant reports that there are six medical and eight surgical oncologists on the AMC medical staff. There are also three gynecological oncologists from UVa on the AMC medical staff.

2. Facilities providing radiation therapy services should have written policies and procedures for concurrent, retrospective, and prospective consideration of cancer cases by an in-house multi-specialty tumor board or committee per American College of Surgeons accreditation guidelines.

AMC has an active multi-disciplinary tumor registry in place with written policies and procedures.

3. Facilities providing radiation therapy services should have available support services such as nutrition information, physical therapy, and social and vocational rehabilitation to assure that the patient attains the optimal functional capacity during and after course treatments.

Various ancillary and support services, including nutrition counseling, physical therapy and social and vocational rehabilitation, are available at AMC.

D. There should be adequate space in the therapeutic radiation treatment facility to provide for: (i) reception and waiting areas; (ii) consultation and examination; (iii) planning and conferences; (iv) work and utility areas including stretcher and wheelchair space; (v) treatment units; (vi) mechanical and supporting facilities; (vii) record storage; and (viii) a recovery area.

The proposed project has been designed with the benefit of the most current thought as to appropriate and effective design. Adequate space for various purposes have been integrated into the proposed service's physical plant.

3. The relationship of the project to the long-range development plan, if any, of the person applying for a certificate.

AMC has presented no formal long-range development plan. Regardless, AMC's application reveals an undertaking consistent with a formal strategic planning process, including such facets as community assessments, physician surveys, stakeholder analysis and capital requirements. AMC also maintains that establishing radiation therapy services have been a part of AMC's development plan since the original hospital plan and design were formulated, due mainly to recognition of cancer as a major cause of mortality and morbidity the hospital's service area.

Notably, the proposed project exhibits a commendable systems-based approach to the development of health care services through the partnership of an academic medical center and two community hospitals in jointly planning and operating the proposed service.

4. The need that the population served or to be served by the project has for the project, including, but not limited to, the needs of rural populations in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

AMC's primary service area of Augusta County, Staunton, and Waynesboro has a population of approximately 110,000. Three additional counties for which AMC is an important source of hospital services, Rockbridge, Bath, and Highland Counties, contain an additional 28,000 residents.

This population is served mainly by the radiation therapy facilities in Harrisonburg and Charlottesville. Most of the people residing in AMC's service area are generally able to reach these cities, or the radiation therapy facilities in Roanoke, within the travel time standard of one hour, under good weather and traffic conditions. As discussed in detail above, however, travel times of 45 minutes to an hour or more for ill and elderly patients who may need to traverse mountainous terrain can represent a significant barrier to obtaining treatment over the several weeks that a typical course of radiation therapy might be administered. These problems are magnified in the case of newer modalities of treatment, in

which radiation therapy and chemotherapy are combined in a single treatment episode, or in which radiation therapy treatments are divided into smaller doses provided on the same day, but several hours apart – a beneficial new approach known as hyperfractionated radiation.

The introduction of radiation therapy services at AMC has strong intrinsic justification because AMC is a hospital well situated to serve a geographic population which is large enough to support the project and large enough to represent a considerable improvement in access to this service for the region's population. Additionally, the proposed project would introduce intensity modulated radiation therapy (IMRT), which delivers radiation more precisely to a tumor, while sparing more of the surrounding normal issue. (IMRT treatment, however, lengthens treatment time by as much as two to three times that of standard radiation therapy.) Despite the potential for the proposed project to contribute marginally to the continued underutilization, as gauged by the SMFP provisions drafted in the early 1990s, of radiation therapy services located in Harrisonburg and Charlottesville, its approval would directly provide an important service to a population that presently has only fair to marginal geographic access to these services.

Notably, many people in AMC's service area, particularly the elderly, have a cultural predilection to remain in the rural area of the Shenandoah Valley or the mountainous regions in which they live. Many of these people appear to have little desire to leave the area to visit Charlottesville or Harrisonburg, especially if doing so means having to travel by Interstate highway. Such an aversion to travel can have the effect, as Senator Hanger related in his letter, discussed above in relation to 12 VAC 5-340-30, of a patient choosing to forego prescribed and needed therapy. When receiving radiation therapy services, Delegate Landes related in his letter and testimony at the IFFC, patients are often nauseated, severely fatigued, experiencing difficulty breathing and are dealing with the side effects of cancer and other treatments including chemotherapy and surgery. Adding a significant travel burden often causes patients to choose sub-optimal treatment options.

5. The extent to which the project will be accessible to all residents of the area proposed to be served.

The proposed project would be more geographically accessible to the residents of the cities of Staunton and Waynesboro, a large portion of Augusta and Rockbridge counties and parts of Bath, Highland, Nelson and Albemarle Counties than existing radiation therapy services.

AMC has established a good record of charity health care contributions – the fifth highest as a percent of gross revenues in HPR I. The project promises considerable improvements in access to radiation therapy services.

6. The area, population, topography, highway facilities and availability of the services to be provided by the project in the particular part of the health service area in which the project is proposed, in particular, the distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

AMC's primary service area is Augusta County and the cities of Waynesboro and Staunton. The hospital's secondary service area includes portions of Bath, Highland and Rockbridge counties, in PD 6, and the western portions of Nelson and Albemarle counties, in PD 10. The area, which AMC

contends covers over 2,500 square miles, is traversed by Interstate highways 81 and 64. Interstate 81 is a major and heavily-used thoroughfare for the commercial transport by tractor-trailor of goods along the eastern seaboard, often making its use by occupants of passenger vehicles less than pleasant and, at times, stressful, marked by unpredictable delay and dangerous. Interstate 64 crosses through a pass over Afton Mountain between Waynesboro and Staunton. Traveling via Interstate 64 through this pass involves negotiating a gradient exceeding five degrees in both an easterly and a westerly direction and is often complicated by dense fog and severe winter weather conditions, only partially assuaged by a special roadway lighting system.

AMC is the only hospital located in Augusta County, which, in terms of land area, is the second largest county in Virginia, covering over 900 square miles of rural and mountainous terrain. AMC is also the nearest hospital to a large portion of geographically-dispersed residents in Bath, Highland, Rockbridge, Nelson, and Albemarle counties.

While a considerable portion of this area appears geographically proximate to AMC, travel times from points such as Buffalo Gap, Millboro Springs and Augusta Springs to AMC frequently exceed more than an hour. Travel by road in these areas involve negotiating the prevailing mountainous terrain over secondary state roads, some of which are paved with loose gravel. These physical barriers impede travel under the best conditions and are made more challenging by poor and inclement weather.

Testimony received at the IFFC, statements in letters, and over two dozen testimonials volunteered by area residents and directed to the State Health Commissioner via email discuss these difficulties and a certain cultural aversion to highway travel that may contribute to patients' deciding to forego prescribed treatment located at distant sites. Several of these statements relate personal experience or a family member's experience with the challenges of traveling from home to receive numerous radiation therapy treatments at UVa and RMH.

Notably, the proposed project, as a venture of Valiance (which includes UVa and RMH), would enhance the provision of radiation therapy services in the extended area by allowing AMC, UVa and RMH to coordinate the provision of these services by providing them in the most accessible location for patients by directing them to the most conveniently accessible site under prevailing circumstances.

7. Less costly or more effective alternate methods of reasonably meeting identified health service needs.

While denial of this project would clearly be a less costly alternative for AMC and Valiance, such action would continue the expectation that the population to be served rely on existing radiation therapy facilities. Denial would have the effect of leaving demonstrated barriers to access unaddressed and, in some cases, preventing access to services for this population, as noted above. The benefits of improved access and the establishment of a broader continuum of cancer treatment at AMC would not be realized under this alternative, and the costs imposed on the population by the lack of a locally available radiation therapy service would continue and grow with the population's growth and aging.

8. The immediate and long-term financial feasibility of the project.

The construction portion of the projected will be funded from the accumulated reserves of AMC. Capital equipment needs will be financed through a conventional loan assumed by Valiance. Based on a statement of operations devised by AMC, the proposed project appears financially feasible in the immediate and long-term, with a projected profit margin exceeding six percent and projected net income exceeding $147,000 annually.

9. The relationship of the project to the existing health care system of the area in which the project is proposed; however, for projects proposed in rural areas, the relationship of the project to the existing health care services in the specific rural locality shall be considered.

The proposed project reflects highly commendable qualities of sound health planning by employing a systems-based approach to augmenting health care. The project would introduce a beneficial service to a predominantly rural area and directly involve two community hospitals and an academic medical center, which have collaborated in the creation of a specific entity, Valiance, to coordinate such ventures. In doing so, the proposal promises a beneficial relationship to existing health care services, without any reasonable expectation that its approval would disrupt current clinical services.

10. The availability of resources for the project.

Funding for this project would come from the accumulated reserves of AMC and a conventional loan. Necessary staff are available through the Valiance partnership.

11. The organizational relationship of the project to necessary ancillary and support services.

Since the proposed radiation therapy service would be a part of the physical structure of AMC – an established community hospital, necessary ancillary and support services would be available.

12. The relationship of the project to the clinical needs of health professional training programs in the area in which the project is proposed.

Not applicable.

13. The special needs and circumstances of an applicant for a certificate, such as a medical school, hospital, multidisciplinary clinic, specialty center or regional health service provider, if a substantial portion of the applicant's services or resources or both is provided to individuals not residing in the health service area in which the project is to be located.

Not applicable.

14. The special needs and circumstances of health maintenance organizations. When considering the special needs and circumstances of health maintenance organizations, the Commissioner may grant a certificate for a project if the Commissioner finds that the project is needed by the enrolled or reasonably anticipated new members of the health maintenance

organization or the beds or services to be provided are not available from providers which are not health maintenance organizations or from other health maintenance organizations in a reasonable and cost-effective manner.

Not applicable.

15. The special needs and circumstances for biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.

Not applicable.

16. In the case of a construction project, the costs and benefits of the proposed construction.

Introducing radiation therapy services requires specialized construction of relatively expensive facilities to house the radiation therapy equipment. The flexibility in constructing or reconfiguring physical space that exists for many other types of health care services is not present.

In this case, AMC has chosen to develop a facility that includes all of its oncology programs and to provide a platform for additional space that it may sell or lease to physicians, as well as the proposed radiation therapy service. By placing these two related projects in close proximity and within the same structure, a significant savings in space and construction costs accrues. Additionally, the cost of the project, as set forth in terms of cost per gross square foot, appears reasonable.

17. The probable impact of the project on the costs of and charges for providing health services by the applicant for a certificate and on the costs and charges to the public for providing health services by other persons in the area.

The estimated costs and projected charges for providing radiation therapy at AMC appear higher than those associated with similar projects reviewed by within the past year. Reimbursement for these services, however, are negotiated, for the most part, with third party payors, so projected costs often are not borne out in reality. Since the proposed project reflects collaboration with UVa and RMH – both of which provide radiation therapy services – certain efficiencies such as the sharing of staff, protocols, education and training may serve to reduce projected costs and charges.

18. Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost effectiveness.

While the proposed project cannot be seen to promise improvement or innovation that fosters competition, it represents a commendable effort to engage in systems planning, and presents an opportunity to promote quality assurance and cost effectiveness by improving access and collaboration between AMC, UVa and RMH.

19. In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities in the area similar to those proposed,

including, in the case of rural localities, any distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

Valiance, of which UVa and RMH are members, recognizes that the development of radiation therapy services at AMC would likely result in a new pattern of referral in which some area patients who would have been referred to UVa or RMH for radiation therapy services would, instead, be referred to AMC for those services.

The establishment of radiation therapy services at AMC would reduce travel time in its large, predominantly rural primary and secondary service areas. The project would address various effects of the prevailing socioeconomic and geographic conditions faced by the mostly rural population. A high level of poverty prevails in a large portion of the service area, which consists of an aging population without adequate access to transportation to UVa or RMH. Mountainous terrain and highway congestion make travel difficult, particularly in inclement weather, and at times, results in patients' forbearance of radiation therapy services.

20. The need and the availability in the health service area for osteopathic and allopathic services and facilities and the impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels.

The proposed service would provide opportunities for the teaching and training of physicians and various medical and technical staff at UVa.

C. RECOMMENDATION

I have reviewed the application and subsequent submissions of Augusta. I have heard from counsel to the applicant in support of its application, and from the staff of the Division of Certificate of Public Need who evaluated the proposal. I have considered the recommendation issued by the board of directors of the Northwestern Virginia Health Systems Agency (NVHSA).

Based on my assessment, I have concluded that the application submitted by Augusta Medical Center (AMC) to introduce radiation therapy services in Augusta County merits approval and should receive a certificate of public need (COPN), subject to the following two conditions, as authorized by Virginia Code Section 32.1-102.2 C, *viz*., that:

> **Condition Number One: AMC will ensure that radiation therapy services will be provided to persons in need of such services, regardless of their ability to pay, and will provide as charity care to indigent patients free radiation therapy services or rate reductions for such services in an aggregate annual amount equivalent to at least 1.6 percent of gross patient revenue derived from radiation therapy services; and**
>
> **Condition Number Two: AMC will provide annually to DCOPN and NWVHSA an audited or otherwise certified financial statement documenting compliance with the preceding condition for the first three years following operation of radiation therapy services. (The obligation to continue providing charity care in accordance**

with Condition Number One, above, will continue indefinitely and beyond the first three years of operation.)

The specific reasons for my recommendation include:

(i) The proposed project would greatly improve access to radiation therapy – a service that is increasingly important to sustaining life in an aging population and typically involves daily treatment of a patient and side effects over a period of several weeks – for residents of the intended rural service area, who must often contend with limitations imposed by geographical boundaries and challenges relating to transportation;

(ii) The proposed project is substantially compliant with applicable standards and provisions of the State Medical Facilities Plan (SMFP);

(iii) The Northwestern Virginia Health Systems Agency (NWVHSA) recommended approval of the proposed project, conditioned on the provision of charity care, noting that the project complied with all applicable provisions of the SMFP except one numerical methodology designed to gauge need "that is outdated;"

(iv) AMC's proposed project reflects a commendable effort to actualize sound, system-based health planning, and would involve the close cooperation and assistance of the University of Virginia Medical Center (UVa) and Rockingham Memorial Hospital (RMH) – the two facilities providing radiation therapy services most likely to be affected by approval of the AMC proposal; and

(v) The experience and expertise resulting from the involvement of UVa and RMH in implementing and operating AMC's proposed project would provide helpful models for treatment, beneficial operational protocols, and specialized staff and medical direction for the proposed project.

Respectfully submitted,

Douglas R. Harris, J.D.
Adjudication Officer